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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,272	07/17/2003	Shanta M. Modak	A35008-PCT-USA-A (070050).	4202
21003 7590 01/05/2007 BAKER & BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			EXAMINER ANDERSON, JAMES D	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,272	<b>Applicant(s)</b> MODAK ET AL.	
	<b>Examiner</b> James D. Anderson	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-17, drawn to an anti-irritant composition comprising two or more water-soluble, organic salts of zinc, classified in class 424, subclass 642. Please note additional Election of Species requirements outlined below if Group I is elected.
- II. Claim 18, drawn to an anti-irritant composition comprising a synergistic amount of chlorhexidine gluconate, benzyalkonium chloride and incroquat, and further comprising other inactive ingredients, classified in class 424, subclass 400+.
- III. Claims 19-30, drawn to a method of decreasing irritation of the skin or mucous membranes comprising applying the anti-irritant composition of claim 1, classified in class 514, subclass 494.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related anti-irritant compositions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed comprise distinct active ingredients. For example, the compositions of group I require two or more organic salts of zinc. The compositions of group II have no such requirement.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is

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nothing of record to show them to be obvious variants. This is further evidenced by the different classification of the two distinct groups.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compositions of group I comprising organic zinc salts could be used as anti-viral lubricants to effectuate the inactivation of HIV-1 or other viruses implicated in the spread of sexually transmitted diseases (U.S. Patent No. 5,940,477) (cited by applicants).

Inventions II and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method of use recited in the claims of group III require a composition as recited in claim 1. Said composition is distinct from the composition recited in the claim of group II as evidenced by their separate classification.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

***Election of Species Requirements if Group I is Elected***

Claim 5 is generic to the following disclosed patentably distinct species: the distinct emollients recited in the claim. The species are independent or distinct because the emollients recited in the claim are materially different, with different properties and structures. As such, the search for one particular emollient would be different than the search for another. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 7 is generic to the following disclosed patentably distinct species: the distinct gelling or thickening agents recited in the claim. The species are independent or distinct because the gelling and thickening agent recited in the claim are materially different, with different properties and structures. As such, the search for one particular gelling or thickening agent would be different than the search for another. Applicant is required under 35 U.S.C. § 121 to

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elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 8-9 are generic to the following disclosed patentably distinct species: the distinct silicone polymers encompassed by the claims. The species are independent or distinct because the silicone polymers recited in the claims are materially different, with different properties and structures. As such, the search for one particular silicone polymer would be different than the search for another. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 10-11 are generic to the following disclosed patentably distinct species: the distinct antimicrobial agents encompassed by the claims. The species are independent or distinct because the antimicrobial agents recited in the claims are materially different, with different chemical properties and structures. As such, the search for one particular antimicrobial agent would be different than the search for another. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

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allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 12-13 are generic to the following disclosed patentably distinct species: antioxidants and surfactants. The species are independent or distinct because antioxidants and surfactants are materially different, with chemical properties and structures. As such, the search for antioxidants would be different than the search for surfactants. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 16 is generic to the following disclosed patentably distinct species: the multitude of compounds encompassed by "natural or synthetic chemicals". The species are independent or distinct because the claimed chemicals are materially different, with chemical properties and

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structures. As such, the search for, for example, almond oil would not be the same as a search for a monoterpene hydrocarbon. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. This election of species requirement will be withdrawn if applicants state on the record that the disclosed species are obvious variants of each other. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

### ***Joint Inventors***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Patent Examiner  
AU 1614

December 22, 2006



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PRIMARY EXAMINER